

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,

Petitioners,

v.

THE FOUNDRY, LLC.,

Patent Owner.

Case No. IPR2024-00281

U.S. Patent No. 11,679,077

**DECLARATION OF DR. GREGORY T. MARTIN
REGARDING CLAIM 4 OF U.S. PATENT NO. 11,679,077**

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I, Gregory T. Martin, Ph.D., declare as follows:

I. INTRODUCTION

1. My name is Gregory T. Martin.

2. I am making this declaration at the request of Neurent Medical Inc. and Neurent Medical Ltd. (“Neurent” or “Petitioners”) as an independent expert consultant in this proceeding before the United States Patent and Trademark Office and to provide testimony pertinent to Petitioners’ Petition for *Inter Partes* Review of U.S. Patent No. 11,679,077 (the “’077 patent”). I understand that Petitioners are challenging the patentability of claims 1-8 and 11 of the ’077 patent (“Challenged Claims”). As detailed below, I have been asked to offer opinions regarding claim 4 as it relates to Ground III (Saadat and Stern) and Ground VI (Makower, Fang, Edwards-535, and Stern).

II. QUALIFICATIONS AND EXPERIENCE

3. My qualifications for setting forth the opinions in this declaration are summarized below. My curriculum vitae, which describes *inter alia* my education, experience, professional activities, my publications, and patents, is attached as **Appendix A**.

4. I received my Bachelor of Science (in 1988), Master of Science (in 1991), and PhD (in 1995), all in mechanical engineering, from the Massachusetts Institute of Technology (MIT).

5. I have over two decades of experience designing and developing medical devices, with a focus on energy-based medical devices. From 1998-2000, I was the Vice President of Research and Development, and Corporate Director, for Thermal Technologies, Inc., a medical device incubator and contract research company that developed technologies for the measurement of tissue blood flow, cardiac output, tissue oxygen concentration, radiotherapy dosage and tumor temperature for use in hyperthermia therapy. From 2000-2007, I was the co-founder, Chief Technology Officer, and Corporate Director for Hemedex, Inc., a medical device start-up that developed and commercialized a device—a minimally invasive catheter with monitor and software—to monitor cerebral blood flow at the bedside in neurosurgery patients with traumatic brain injury, cerebro-vascular disease and stroke. In 2007, I served as the Vice President of R&D for Cytac Corporation, a company that developed and commercialized medical devices including for treatment of menorrhagia, breast cancer with radiotherapy, and brain cancer with radiotherapy. From 2007-2011, I served as the Vice President of R&D for Hologic, Inc., a leading women's health company, where I was responsible for developing devices in the Surgical Products Division—including tissue ablation medical devices. From 2017-2018, I served as Vice President of R&D for Opsonix, Inc., where I developed a device-biologic combination product and companion diagnostic

to remove pathogens and endotoxins from blood via an extracorporeal circuit. Between 2012-2013 and since 2018, I have been a Principal at Tremont Consulting, LLC, where I provide consulting services in the medical device and diagnostics industries.

6. Throughout my career designing medical devices and diagnostics, I have routinely consulted with medical practitioners. This includes, but is not limited to, consulting medical journals and discussing design, performance, and treatment criteria with medical practitioners.

7. In addition to my work in industry, I have also served as Senior Lecturer in Boston University's Department of Biomedical Engineering from 2013-2017 and from 2019-2020. In that capacity, I taught classes on medical device product design in biomedical engineering (to undergraduates, and to graduate students), and on healthcare entrepreneurship. I have published more than 20 peer-reviewed scientific articles and have 9 issued U.S. patents, including Martin, et al., *Theoretical analysis of localized heating in human skin subjected to high voltage pulses*, 57 BIOELECTROCHEMISTRY 55-64 (July 1, 2002) and U.S. Patent No. 8,814,796 to Martin et al. (Aug. 26, 2014), titled "System and method for tissue ablation in a body cavity."

8. I am being compensated for my work in this matter at my standard consulting rate of \$400 per hour. However, my opinions are based on my own understanding of the prior art, the knowledge of a person of ordinary skill in the art, and the patent at issue. My compensation is not dependent on and in no way affects the content of my statements, opinions, or conclusions in this declaration nor does it affect any testimony I give or on the outcome of this proceeding.

9. I have no financial interest in Petitioners. I similarly have no financial interest in the '077 patent and have had no contact with the named inventors of the '077 patent.

III. LEGAL PRINCIPLES

10. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my opinions. My understanding of the law was provided to me by Petitioners' attorneys.

A. Scope of Opinion

11. I have been informed and understand that the petitioner in an *inter partes* review may request cancellation of claims as unpatentable only on grounds that such claims are anticipated or would have been obvious to a person of ordinary skill in the art at the time of the purported invention, and only on the basis of prior

art consisting of patents or printed publications. My opinions in this matter address only such grounds.

B. Anticipation

12. I have been informed by counsel that a patent claim is anticipated and therefore unpatentable if each element of that claim is present in a single prior art reference.

C. Obviousness

13. I understand that a claim is unpatentable if it would have been obvious to a person of ordinary skill in the art at the time the alleged invention was made. I understand that a claim could have been obvious based on the teachings or suggestions of a single prior art reference or from a combination of two or more prior art references. I understand that an obviousness analysis requires an understanding of the scope and content of the prior art, any differences between the alleged invention and the prior art, and the level of ordinary skill in evaluating the pertinent art.

14. I further understand that a claim would have been obvious if it unites old elements with no change to their respective functions, or alters prior art by mere substitution of one element for another known in the field, and that combination yields predictable results. Also, I understand that obviousness does not require

physical combination/bodily incorporation, but rather consideration of what the combined teachings would have suggested to persons of ordinary skill in the art at the time of the alleged invention.

15. In connection with obviousness, I have been informed that there must have been some reason or motivation that would have led a person of ordinary skill in the art to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so.

16. While it may be helpful to identify a reason for this combination, I understand that there is no rigid requirement of finding an express teaching, suggestion, or motivation to combine within the references. If a person of ordinary skill in the art can implement a predictable variation, obviousness likely bars its patentability. For the same reason, if a technique has been used to improve one device and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique would have been obvious. I understand that a claim would have been obvious if a person of ordinary skill in the art would have had reason to combine multiple prior art references or add missing features to reproduce the alleged invention recited in the claims.

17. In sum, I understand that a determination of whether a claim would have been obvious is based upon a variety of considerations, including, among others:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, which, when combined, would yield predictable results;
- whether a person having ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person having ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the alleged invention applies a known technique that had been used to improve a similar device or method in a similar way.

18. I also understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered. I also understand that one of ordinary skill in the art has ordinary creativity, and is not an automaton.

19. I further understand that certain factors, commonly referred to as secondary considerations, may support or rebut the obviousness of a claim. I also understand that secondary considerations cannot be used to overcome anticipation. I understand that such secondary considerations include, among other things, commercial success of the patented invention, skepticism of those having ordinary skill in the art at the time of invention, unexpected results of the invention, any long-felt but unsolved need in the art that was satisfied by the alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus, that is, a connection, between any such secondary considerations and the alleged invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

20. I reserve the right to respond to any allegations that may be put forth by Patent Owner in this proceeding that any secondary considerations tend to rebut the obviousness of any claim of the '077 patent discussed in this declaration.

D. Claim Dependency

21. I understand that a patent may include two types of claims, independent claims and dependent claims. An independent claim stands alone and includes only

the limitations it recites. A dependent claim can depend from an independent claim or another dependent claim. I understand that a dependent claim includes all the limitations that it recites in addition to all of the limitations recited in the claim or claims from which it depends.

* * *

22. The analysis in this declaration is in accordance with the above-stated legal principles.

IV. MATERIALS CONSIDERED

23. In preparing this declaration, I reviewed and considered the materials cited in this declaration and in **Appendix B** as well as any document cited in this declaration. I have also relied on a conversation with Dr. Nicolas BuSaba and have reviewed his declaration.

V. LEVEL OF ORDINARY SKILL IN THE ART

24. It is my understanding that when considering the claims of the '077 patent and the prior art, I must do so based on the perspective of one of ordinary skill in the art at the relevant effective priority date.

25. I have been informed and understand that the '077 patent claims priority to a series of patent applications, starting with a provisional application filed on July 22, 2005. *See* Ex.1001-USP077, Cover. I also understand that

the '077 patent claims priority to U.S. Patent No. 10,610,675 (the "'675 patent") which was filed on October 22, 2019. I understand that it is Petitioners' position that the '077 patent is only entitled to a priority date of the filing date of the '675 patent, which is October 22, 2019. For purposes of my analysis, I have considered the level of ordinary skill in the art as of July 2005 and as of October 2019. In my opinion, that level was the same for all relevant times between 2005 and 2019.

26. I understand from Petitioners' counsel that several factors are to be considered in determining who would be a person of ordinary skill in the art. These factors include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field.

27. Based on these factors as well as my experience and expertise, a person of ordinary skill in the art ("POSITA") at relevant times (2005-2019) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including

medical devices that deliver energy to tissue. A higher level of education may compensate for less work experience, and vice versa.

28. Although my qualifications and experience exceeded those of a POSITA as defined above between 2005 and 2019, my analysis and opinions herein regarding the '077 patent have been based on the perspective of a person of ordinary skill in the art as of the relevant times of the '077 patent (2005-2019).

VI. OVERVIEW OF THE TECHNOLOGY

A. An Overview of Radiofrequency (“RF”) Ablation

29. RF ablation utilizes high frequency alternating electrical voltage or current—generally between 300kHz-700kHz—to modify tissue. As an alternating voltage is applied to tissue, small ions in the tissue start to move, which facilitates current flow and creates friction that generates heat in the tissue. The increase in temperature damages portions of tissue and/or kills tissue cells, creating lesions. These lesions are formed at therapeutically advantageous locations, such as to tissue containing a nerve to prevent the nerve from sending signals.

30. RF ablation devices for the treatment of chronic pain have been known for decades. *See* Ex.1069-Koyyalagunta, 4-6. For example, in 1931, RF ablation was used to target the gasserion ganglion, a nerve in the head, and to treat the Trigeminal neuralgia. *Id.*, 6. Since their introduction several decades ago, and long

before the '077 patent, many RF ablation devices have been used as medical devices, for example, to destroy a blockage, treat tissue, or shrink tissue. *See, e.g.*, Ex.1008-Edwards-535, Abstract (“By reducing the size of a nasal concha, obstruction of a nasal meatus is reduced or eliminated”); Ex.1081-Baker, 5:59-65 (delivering RF energy to the endometrial lining of a patient’s uterus); Ex.1080-Goble, 3:35-48 (using RF energy to treat “the bladder, the gall bladder, portions of the gastrointestinal tract, the heart, ... hemorrhoids, intestinal walls, the lining of the rectum, the lining of the bladder...”); Ex.1082-Hovda, 11:13-31 (providing “ablation and hemostasis of swollen or enlarged structures in the nose, such as turbinates”).

31. Prior to 2005, many devices incorporated RF ablation technology and different components needed to deliver RF energy. Most had similar features, like handles and shafts that were flexible and steerable. *See* Ex.1081-Baker, 5:27-47; Ex.1005-Makower, [0187].

32. Electrically, these devices were capable of either bipolar or monopolar configurations, or both. *See, e.g.*, Ex.1081-Baker, 5:47-58; Ex.1080-Goble, 6:33-68; 11:23-49. These devices involved the use of multiple electrodes, either bipolar or monopolar depending on the configuration. Ex.1080-Goble, 6:33-68; 11:23-49. Some of these electrodes could penetrate target tissue, for example, if they were

needle electrodes (sometimes referred to as “penetrating electrodes”), Ex.1066-Edwards-886, 26:54-28:8, or the electrodes could be surface electrodes and only contact the surface of tissue without puncturing it (sometimes referred to as “non-penetrating electrodes”), Ex.1008-Edwards-535, 4:55-60; Ex.1081-Baker, 5:47-58. Such devices could target tissue underneath the surface without ablating the surface tissue, for example by penetrating the tissue to a desired depth (as is the case for needle electrodes) or by cooling the surface of the tissue, thereby allowing only the subsurface tissue to heat (*see, e.g.*, Ex.1008-Edwards-535, 4:60-65). Cooling systems could also be used in general to avoid overheating tissue. Ex.1066-Edwards-886, 2:60-65.

33. The ways in which RF energy could be delivered to tissue and modify that tissue’s properties were well studied and understood by the early 2000s. One common way of delivering RF energy was to contact RF electrodes directly with target tissue and apply RF current to the tissue to introduce heat, which thereby destroys the tissue. Ex.1008-Edwards-535, 5:27-32 (“[E]xpandable member 132 is brought into contact with the surface 115 of the nasal concha 114 to be treated” and “[a]blative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal concha 114.”), 8:12-14 (“the energy delivery device may be positioned on a surface 147 of the expandable member,” which would then

be used to apply energy through contact with tissue rather than through any intermediary heating device), 8:26-39 (describing function of similar surface-mounted electrodes); Ex.1044-Chen, 240 (describing placing a probe on the tissue surface to apply energy); Ex.1009-Stern, 3:12-15 (“electrode...for effecting electrical contact with tissue of said body organ.”), 3:12-15 (“According to the invention there is provided an apparatus for selectively applying RF energy to a body organ. The apparatus comprises an electrode means for effecting electrical contact with tissue of said body organ....”).

34. Many devices included systems that would help the clinician monitor the treatment, like visualization capabilities and guidance, Ex.1008-Edwards-535, 10:39-45, Ex.1080-Goble, 2:17-20, and temperature and impedance sensor feedback, Ex.1008-Edwards-535, 9:14-11:44.

B. Monopolar and Bipolar RF Electrode Configurations

35. Prior to 2005, RF ablation devices could be configured in monopolar and/or bipolar configurations. Both use electrical current flowing from a generator to an active electrode (+), and then the current flowing back to a return electrode (-).

36. In a monopolar configuration, current passes from an active electrode (+), through the tissue contacting the active electrode, and then out of the patient to a return electrode (-), typically a grounding pad placed on the patient’s body. A

depiction of a monopolar scheme from Ex.1009-Stern, Figure 16 is copied below. In that figure, current (shown by electrical field lines) passes from the active electrodes 252 and 256 to the return electrodes (not shown).

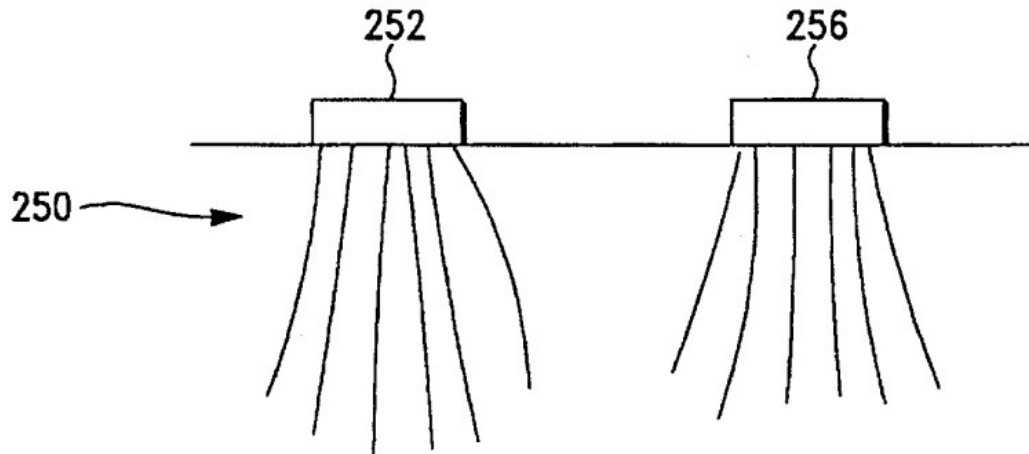


FIG. - 16

Ex.1009-Stern, FIG.16.

37. In a bipolar configuration, as depicted in Ex.1009-Stern's Figure 17 copied below, current flows from an active electrode (258 in Stern's Figure 17), through the tissue contacted by the active electrode, to a return electrode (260 in Stern's Figure 17) located near the active electrode. Because the active and return electrodes are close in proximity, the electrical field lines are more controllable and only travel through a small portion of tissue.

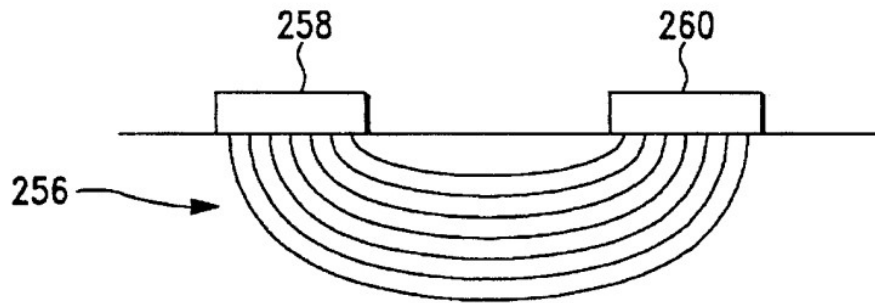


FIG.-17

Ex.1009-Stern, FIG.17. This arrangement allows precise direction of energy and current to specific locations, and may be of particular use when ablating tissue in a patient's head to avoid the current from interfering with the patient's own electrical signals his or her brain. *See* Ex.1082-Hovda, 5:4-18. By the early 2000s, it was well known that this can be safer than a monopolar arrangement, where current flows more broadly through a patient's body to a more distant return electrode. Such uncontrolled and dispersed current could interfere with the electrical signals (e.g., brain signals) in a patient's head.

38. The Stern reference discussed in this declaration also describes how field lines can be more controllable in bipolar configurations. "The ability to control field lines, and therefore the heated area, utilizing bipolar operation is exemplified in FIG. 18 wherein there is a balloon 262 having electrodes 264 and 266 with the field lines passing through the patient in such a way that effectively the bipolar

energy may be directed to flow around the edges of the balloon 262 in order to insure complete heating of an area...” Ex.1009-Stern, 13:21-27. This was a known benefit of using bipolar RF electrodes before 2005. For example, Goble teaches that using bipolar electrodes allows for more granular control over a specific location to heat: “[f]or example, if the system desired...the distal portion of the bladder to have greater heat, just the most distal active electrode 24a and return electrode 26a might be activated.” Ex.1080-Goble, 8:46-57. Likewise, Goble teaches activating the bipolar electrodes in “sets,” for example by using “three active electrodes 24a-c” and “three return electrodes 26a-c” and only activating select pairs of electrodes. *Id.*

VII. OVERVIEW OF THE '077 PATENT

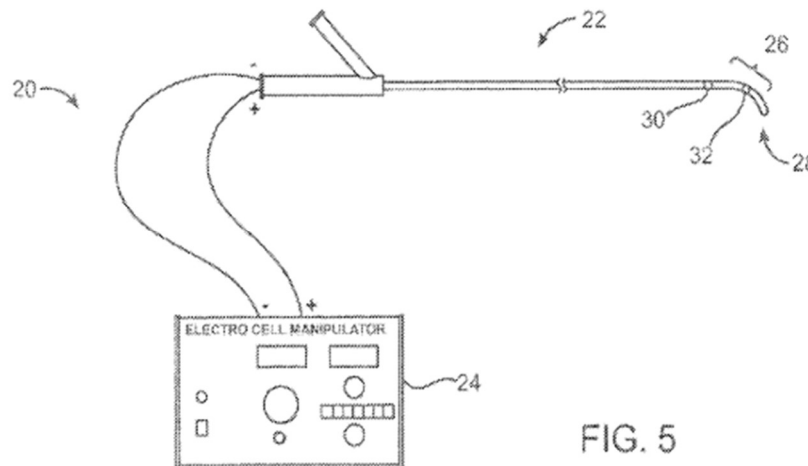
39. The '077 patent relates to “[m]ethods and apparatus[es]...for applying [a] fragment of a neurotoxin such as the active light chain (LC) of the botulinum toxin (BoNT)...via permeabilization of targeted cell membranes to enable translocation of the botulinum neurotoxin light chain (BoNT-LC) molecule across the targeted cell membrane to the cell cytosol where a therapeutic response is produced in a mammalian system.” Ex.1001-USP077, Abstract; *see also id.*, 1:45-47 (“[T]he present invention relates to methods and systems for delivering toxins, such as botulinum toxin light chain fragments, to target cells in a nasal cavity.”), 4:31-45. For example, the '077 patent explains its “methods and systems should be

capable of providing for selective and repeatable delivery of the toxins to defined target areas within the nasal cavities, including particular paranasal sinuses, the nasopharynx, and in some cases substantially the entire nasal cavity” to treat rhinitis. *Id.*, 3:56-4:5, 8:10-28.

40. The '077 patent explains that “neurotoxins” are “delivered to a patient’s nasal membrane while applying energy to target cells within the membrane under conditions which cause a reversible (or in some instances non-reversible) poration of the cell membranes to enhance delivery of the toxin into the cells.” Ex.1001-USP077, 8:10-28; *see also id.*, 13:34-47 (“For purposes of this specification, the term ‘poration’ includes various forms of electroporation...to create temporary pores in a targeted cell membrane. Similarly, the term ‘electrode’ or ‘energy source’ used herein, encompasses the use of various types of energy producing devices...adapted and applied in ranges to produce membrane permeabilization in the targeted cell.”).

41. The '077 patent states that “electroporation may be achieved utilizing a device adapted to activate an electrode set or series of electrodes to produce an electric field.” Ex.1001-USP077, 13:54-14:5. For example, Figure 5 of the '077 patent (below) depicts an “electroporation catheter system” that includes “a first and second electrode 30” that are connected to a generator and apply energy to

cause “reversible cell poration.” *Id.*, 16:42-58. The ’077 patent states that “it may be desirable to incorporate multiple pairs of electrodes that may be activated in pairs, in groups, or in a sequential manner in order to maximize the desired shape of the energy field (EF) while minimizing the field strength requirements.” *Id.*, 18:37-46. The ’077 patent does not explain how to implement “multiple pairs of electrodes.” *See generally, id.*



Id., FIG.5.

VIII. CLAIM CONSTRUCTION

42. I was informed and I understand that, in my analysis, I should give claim terms their ordinary and customary meaning, as understood by a person of skill in the art at the time of the invention. I was informed and I understand that the words of the patent’s claims and the context in which the term is used in the claims

are highly instructive in ascertaining the term's meaning. I further understand that the terms of a claim are to be interpreted in the context of the entire patent, including the patent's claims, its specification, and its figures.

43. I have been further instructed that a patent's prosecution history may often provide helpful evidence about how the U.S. Patent and Trademark Office and the applicant understood the patent and its claims. Therefore, I have been instructed that claim terms should also be interpreted in light of the patent's prosecution history.

44. In addition to the claims, the specification, the figures, and the prosecution history, I have been instructed that certain "extrinsic evidence," such as scientific or technical references, may also help inform the way in which a person of ordinary skill in the art understands the claim term. I have been instructed that extrinsic evidence must always be considered in the context of the intrinsic evidence.

45. For the purposes of this declaration, I will give the claim terms their plain and ordinary meaning, including as understood in the field of the '077 patent, and as understood by a person of ordinary skill in the art. To the extent an express claim construction is proposed in this proceeding or in another proceeding involving the '077 patent, I reserve the right to respond to such a construction and/or propose an express construction consistent with the term's plain and ordinary meaning.

IX. GROUNDS FOR FINDING THE CHALLENGED CLAIMS INVALID

46. I understand that it is Dr. Bu-Saba's opinion that the Challenged Claims are invalid based on the following grounds:

- **Ground I:** Claims 1-3 and 5-8 and 11 are anticipated by Saadat.
- **Ground II:** Claims 3 and 11 are rendered obvious by Saadat.
- **Ground III:** Claim 4 is rendered obvious by the combination of Saadat and Stern.
- **Ground V:** Claims 1-3, 5-8 and 11 are rendered obvious by the combination of Makower, Fang, and Edwards-535.
- **Ground VI:** Claim 4 is rendered obvious by the combination of Makower, Fang, Edwards-535, and Stern.

A copy of the Challenged Claims are attached as **Appendix C**.

47. I have been asked to offer opinions regarding claim 4 as it relates to Ground III (Saadat and Stern) and Ground VI (Makower, Fang, Edwards-535, and Stern).

- **Claim 4:** The apparatus of claim 2, wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.

48. The technical features and structures described in claim 4 were well-known and routinely applied in medical devices in a manner suitable for treating

tissue in a nasal cavity. These structures and features were routinely used and combined with other features of known devices to yield predictable results.

49. In this report, I discuss the following references:

- **Saadat**: U.S. Patent No. 10,307,200 to Saadat (Ex.1003, “Saadat”).
- **Stern**: U.S. Patent No. 5,562,720 to Stern (Ex.1009, “Stern”).
- **Makower**: U.S. Pub. 2005/0240147 to Makower (Ex.1005, “Makower”).
- **Fang**: I understand that Fang (Ex.1006, “Fang”) is an article that was published on July 20, 2005 (Ex.1006-Fang; *see also* Ex.1073 (translation declaration for Fang)).¹

¹ I understand there are two translations of Fang (Ex.1006-Fang and Ex.1079), and I have reviewed both translations. The minor differences between the two translations (*see, e.g.*, Ex.1006-Fang, (“All the patients complied with the diagnostic criteria for perennial rhinitis [1], and were accompanied by **deviated** nasal septum.”); Ex.1079, 31 (“All the patients complied with the diagnostic criteria for perennial rhinitis [1], and were accompanied by **deflected** nasal septum..”)) do not impact my opinions as set forth herein. Therefore, although I cite to Ex.1006-Fang in this declaration, my analysis and opinions applies equally to Ex.1079.

- **Edwards-535**: U.S. Patent No. 6,517,535 to Edwards (Ex.1008, “Edwards-535”).

A. Ground III: Claim 4 In View of the Combination of Saadat and Stern

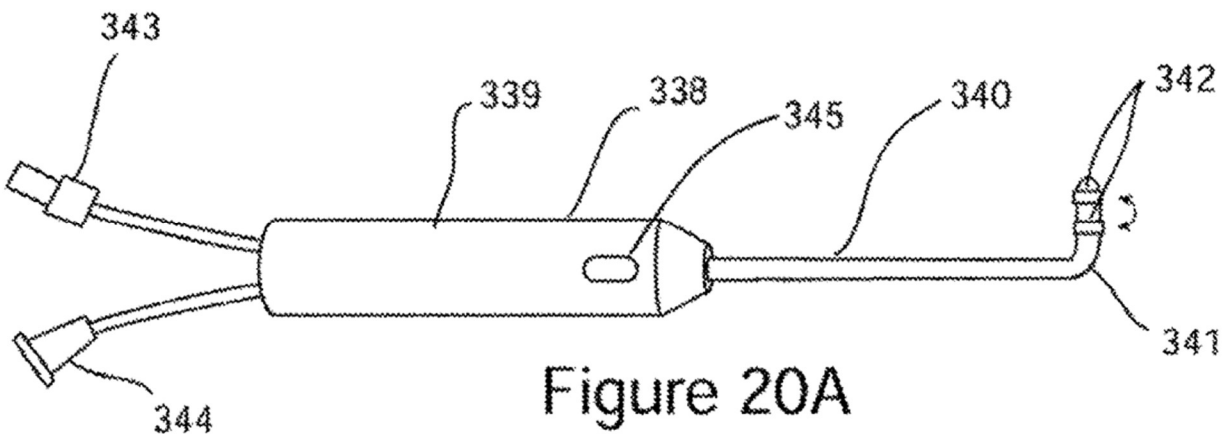
50. Claim 4 recites the following: “The apparatus of claim 2, wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.” As detailed below, it is my opinion that a POSITA would have been motivated to combine Saadat and Stern with a reasonable expectation of success.

1. Saadat

51. Saadat teaches “[a]pparatus[es] and methods for treating conditions such as rhinitis....” Ex.1003-Saadat, Abstract; *see also id.*, 1:21-26, 2:16-24, 3:6-14, 10:16-11:14, claims 1 (claiming a “method for treating nerve tissue within a nasal cavity of a patient”), 6 (claiming “the delivering of the energy-based treatment to treat the nerve tissue underlying the mucosal surface comprises ablating the nerve tissue such that at least one symptom of rhinitis is reduced”).

52. One of Saadat’s disclosed devices is shown in Figures 20A and 20E. Figure 20A (below) “is a schematic illustration of radiofrequency (RF) ablation probe 338 configured for ablation of the parasympathetic nervous function....” Ex.1003-Saadat, 30:34-36. As shown in Figure 20A, the “RF ablation probe 338

comprises handle 339, probe shaft 340, 'J' shaped probe tip 341, bipolar ring electrode pair 342, RF activation switch 345, electrical connector 343, and fluid connector 344." *Id.*, 30:38-41. Saadat teaches that "[e]lectrical connector 343 is configured for connection to a radiofrequency energy generator, for which there are many commercially available." *Id.*, 30:47-49. Saadat also teaches that "RF activation switch 345 allows the user to activate the RF ablation and terminate the RF ablation." *Id.*, 30:54-55.

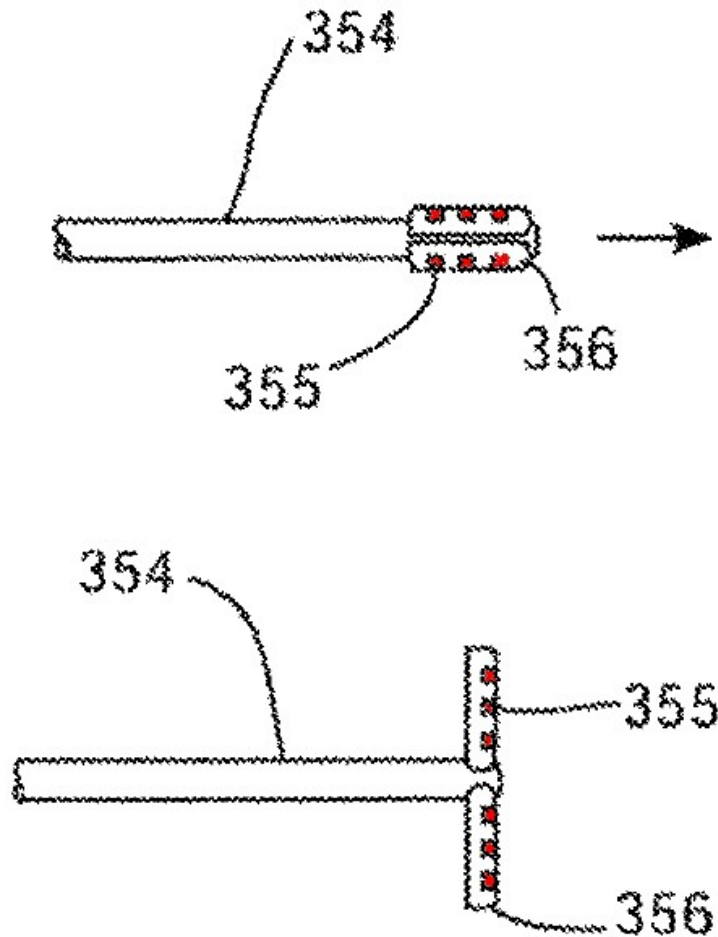


Ex.1003-Saadat, FIG.20A; *see also id.*, 10:16-26 ("In another aspect of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector in the vicinity of the handle configured to connect the RF ablation element to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation

element are optimally configured for RF ablation of PNN function according to the surgical methods disclosed here within.”, 11:1-14 (“Another embodiment of this invention is an electrosurgical probe apparatus for ablation of PNN comprising a handle at the proximal end, a probe shaft with a radiofrequency (RF) ablation element comprising at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft, an electrical connector disposed in the vicinity of the handle configured to connect the RF ablation element, to a source of radiofrequency energy, whereby the geometric parameters of the probe shaft and RF ablation element are optimally configured for RF ablation of PNN according to the surgical methods disclosed here within, wherein the RF ablation element is disposed in the vicinity of the distal end of the shaft on a cylindrical, ‘J’ shaped, ‘U’ shaped or ‘T’ shaped structure.”).

53. Figure 20E (below) discloses an alternative to the “J” shaped tip. Ex.1003-Saadat, 11:1-14, 15:18-21, 31:10-19. Saadat specifically teaches that Figure 20E “is a schematic illustration of the distal end of alternative embodiment 354 of RF ablation probe 338 comprising a bi-polar electrode ablation element 355 on a user deployable ‘T’ shaped structure 356.” *Id.*, 31:10-14. Saadat teaches that the “two halves [of the ‘T’ shaped structure are] collapsed and deployed,” and “are pivoted to allow them to move laterally relative to the catheter shaft 354.” *Id.*, 31:14-

18. Saadat further teaches that the “[e]lectrodes 355” operate in a “bipolar...fashion as known in the art.” *Id.*, 31:18-19. Saadat’s bipolar electrodes are colored in red in Figure 20E below.



Ex.1003-Saadat, FIG.20E. As discussed above in this section, Saadat teaches that its RF ablation probe is a “radiofrequency (RF) ablation probe,” and thus, Saadat’s bipolar electrodes are RF electrodes that deliver RF energy to tissue. *Id.*, 30:34-38, 31:10-19.

54. Although Saadat discloses an RF ablation probe with multiple RF bipolar electrodes and an electrical connector that connects the RF ablation probe to a radiofrequency generator, Saadat does not disclose specific implementation details for Saadat's multiple RF bipolar electrodes. *See, e.g.*, Ex.1003-Saadat, 30:34-41, 47-49. Instead, Saadat explains that “[t]hose skilled in the art of RF ablation probes are familiar with the many possible configurations and construction techniques for RF electrodes and probes that are within the scope of” its teachings. *Id.*, 30:41-47.

2. Stern

55. Stern teaches that the electrodes on the surface of an expandable RF ablation device can be arranged in two rows of bipolar pairs. *See* Ex.1009-Stern, 2:36-40 (“[i]t is a further object of the present invention to provide a system of selective delivery of...bipolar RF energy to chosen pairs of an array of separate electrodes”), 3:29-40, 12:7-13:55, Clm.4, FIGs.13, 15, 17, 18, Title. Stern's electrodes are configured for “selective delivery of either monopolar RF energy to a single electrode or bipolar RF energy to chosen *pairs* of an array of separate electrodes which are used to bring the endometrial temperature to a desired level.” *Id.*, 2:36-40 (emphasis added); *see also id.*, 13:1-44. I show an example of a **bipolar electrode pair (electrodes 258 and 260)** below, from Stern Figure 17:

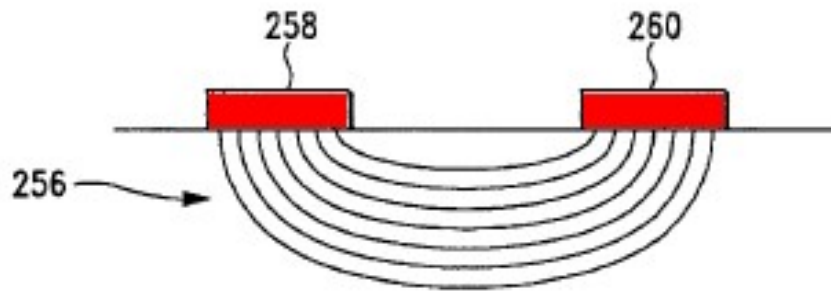


FIG.-17

Ex.1009-Stern, FIG.17. Stern Figure 17 also shows the field lines for the current that travels between the bipolar electrodes. *Id.*, 13:13-14. As shown in Figure 17 above, current travels from one electrode to another. *Id.*

56. Stern's Figure 15, which I have reproduced below, shows the circuitry that controls the bipolar RF energy includes four electrodes 220, 222, 224 and 226 and switches 232-248 that determine which bipolar electrodes are active or return electrodes depending on which switch or switches are open and which are closed. *See* Ex.1009-Stern, 12:41-45 ("within the bipolar mode...the switches allow for the selective application of RF energy to various combinations of electrodes."). Stern teaches examples in which electrodes can be *paired* by closing particular subsets of switches. *Id.*, 12:7-24, 12:37-13:2. One such example would involve the scenario where "switch 248 is closed as well as switch 236" which would result in "bipolar operation" between "electrode 220 and electrode 224." *Id.*, 12:60-63.

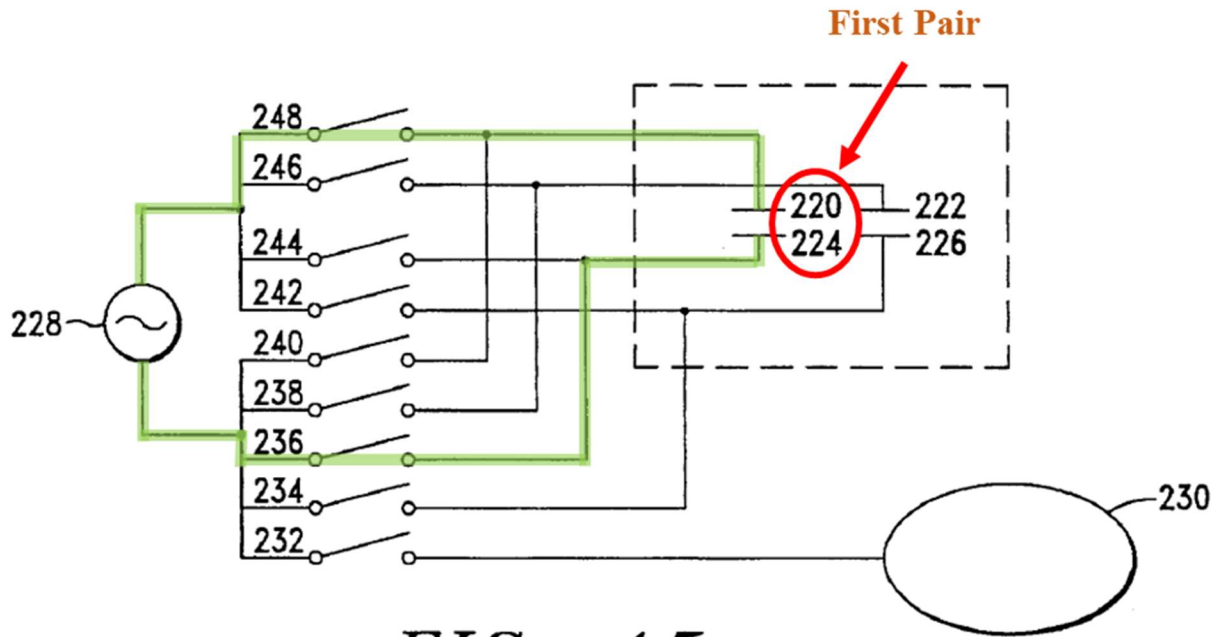


FIG. - 15

Ex.1009-Stern, FIG.15; *see also id.*, 12:46-13:2. Another such example would involve the scenario where “switch 246 is closed as well as switch 234” would result in “bipolar operation” between “electrodes 222 and 226.” *Id.*, 12:63-65.

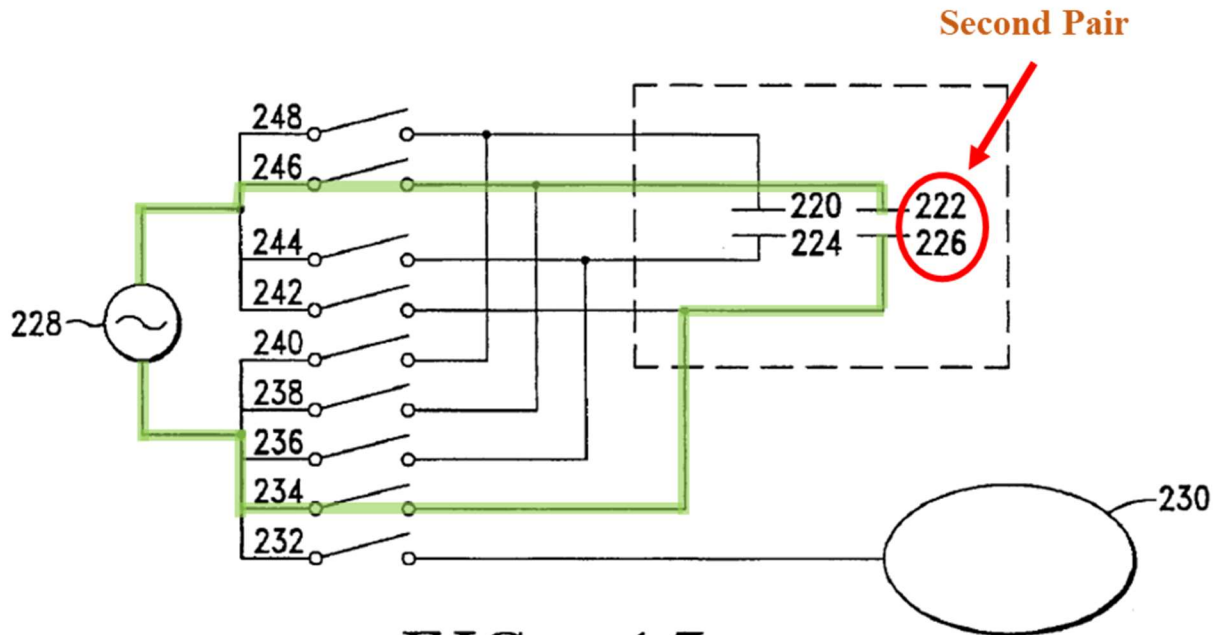


FIG. - 15

Ex.1009-Stern, FIG.15. Stern teaches a well-known and routine way to configure multiple bipolar RF electrodes in pairs. In other words, Stern teaches *two bipolar radiofrequency electrodes that comprise multiple pairs of bipolar radiofrequency electrodes*

3. **Motivation to Combine with a Reasonable Expectation of Success**

57. As I explained in Section III.C (Legal Principles – Obviousness), I have been informed by Petitioners’ counsel and understand that for a claim to be obvious, a POSITA must have had a reason or motivation to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so. It is my

opinion that a POSITA would have been motivated to combine the teachings of Saadat and Stern with a reasonable expectation of success.

58. In my opinion, a person of ordinary skill in the art would have been motivated to incorporate Stern's teaching regarding at least two rows of bipolar electrode pairs into the device in Saadat for several reasons.

59. Saadat discloses delivering RF energy to tissue using bipolar RF electrodes but does not provide details for how to configure its bipolar electrodes. A person of ordinary skill in the art would have been motivated to incorporate the teachings from Stern because it provides detailed information and schematics regarding how to design an RF ablation device with surface electrodes so the electrodes deliver bipolar RF energy and can deliver energy independently through the different electrodes. Stern teaches that its bipolar electrode configuration provides a number of benefits, including providing even heating and precise energy delivery control that are particularly beneficial when trying to ablate an uneven surface.

60. Saadat exemplifies that using RF ablation devices with multiple bipolar surface electrodes in body cavities was well-known. Saadat specifically teaches a "radiofrequency (RF) ablation probe 338 configured for ablation of the parasympathetic nervous function" (*see* Ex.1003-Saadat, 30:34-41, 31:10-22,

FIG.20E), and that is probe includes multiple “bipolar” electrodes that were “known in the art” (*id.*, 31:10-19). However, while a person of ordinary skill in the art would have understood that implementation of bipolar electrodes was routine, Saadat does not provide details on how to implement such energy delivery, leaving it to the skill of a person of ordinary skill in the art. *See id.*, 30:41-47 (“Those skilled in the art of RF ablation probes are familiar with the many possible configurations and construction techniques for RF electrodes and probes that are within the scope of this invention, therefore detailed description of the illustrated, electrode configurations described below, and their construction techniques is not warranted.”). A person of skill in the art would have used Stern’s scheme to implement Saadat’s multiple bipolar electrodes, because Stern provides very detailed schematics and information about how to design a device that can accomplish this goal.

61. A person of ordinary skill in the art would already know how to implement the energy delivery taught by Saadat or would have been motivated to turn to other sources for that information, including regarding how to implement independent energy delivery through each electrode for bipolar energy delivery. When faced with how to independently deliver energy to each electrode or electrode pair, a person having ordinary skill in the art would have had only a limited number

of choices. Specifically, a person of skill in the art would have had to choose whether to use multiple RF generators or just a single RF generator. If using multiple RF generators, electrodes would be individually wired to each generator. If using a single RF generator, circuitry would have been required to control the route of energy (taught by Stern), which could be implemented by switches or relays. A person having skill of the art would have been motivated to use only one RF generator, as was common at the time. Further, a system incorporating only one voltage source is safer (e.g., there are fewer components and more consistency in output for each bipolar pair), more practical (e.g., it would be impractical to use multiple generators when one would suffice, and multiple generators would take up more space in the device), and more reliable (e.g., there would be fewer complex generators that could fail and cause the entire device to be inoperative by virtue of one pair not being useable) than one with numerous power sources. Switches or relays also take up less space than multiple generators, and would have been simpler and cheaper than multiple complex voltage sources.

62. A person of ordinary skill in the art would have been motivated to refer to Stern because it provides detailed information regarding how to design and wire a device that provides RF energy to electrodes independently with a single voltage source. Stern's Figures 5 and 15 provide detailed electrical schematics showing how

to wire and control various sensors and electrodes in a bipolar arrangement. For example, Figure 5 of Stern shows multiple electrodes 50 connected to a switch bank for independent energy delivery, as well as a temperature measurement circuitry including switch bank 52 for each respective electrode. Ex.1009-Stern, 9:2-24, FIG.5. Likewise, Figure 15 shows a flexible circuit that can be used to provide power from a voltage source 228 to any pair of electrodes in the array 220, 222, 224, and 226 for bipolar RF energy application. *Id.*, 12:38-13:2, FIG.15. Stern also provides specific details regarding how to manufacture and arrange electrodes on the surface of an expandable bladder, an example of which is shown in Figure 19. *Id.*, 14:8-60, FIG.19.

63. Further, a person of ordinary skill in the art would have also been motivated to improve Saadat's RF ablation device by configuring Saadat's multiple bipolar RF electrodes in pairs as taught by Stern based on the advantages and benefits of Stern's design, as disclosed in Stern.

64. Stern teaches that pairing bipolar electrodes provides a number of advantages and benefits. ***First***, bipolar electrode pairs allow a user to precisely control the electrical current delivered to tissue, which in turn provides for control of the area being heated. Ex.1009-Stern, 13:21-27 (bipolar pairs provide a user with "[t]he ability to control field lines, and therefore the heated area...to insure [*sic*]

complete heating of an area”), 12:25-37 (bipolar pairs provide a user with “precise control” by selecting “particular pairs” of bipolar electrodes), FIGs.15, 18. This precise control allows a user to selectively ablate a small portion of tissue while leaving other important tissue structures intact. This was an advantage of using bipolar electrode pairs in RF ablation devices that was well known.

65. **Second**, another advantage of energizing electrodes in bipolar pairs is that heat can be directed to targeted tissue while minimizing the chance that tissue that is not being targeted is affected (e.g., not heated and remaining unchanged). This feature—the ability to direct heat to one particular area and not others—is particularly advantageous where target tissue areas have different properties and characteristics (i.e., uneven tissue morphology). Stern expressly teaches this advantage of its electrode arrangement. *See* Ex.1009-Stern, 13:21-39 (“The bipolar arrangement allows various pairs of electrodes to be picked in order to heat uneven or rather asymmetrical areas.... That is, any unusual features within an area to be heated may be taken into account in a bipolar operation by selection of different pairs of electrodes for energization utilizing the circuitry of FIG.15.”), FIG.15. For example, if the targeted tissue has uniform electrical properties, a clinician would apply the same current and voltage to the tissue and expect the same result across the treated tissue. However, the clinician likely would not know whether the

electrical properties of the target tissue are uniform prior to the ablation procedure. If the targeted tissue has uneven morphology, the clinician would be able to apply different currents and voltages at different bipolar pairs for different lengths of time to obtain the same intended result across the uneven tissue. This benefit would be further improved with circuitry that incorporates localized feedback control to allow the clinician to understand the tissue's real-time response to the energy. *See* Ex.1009-Stern, 2:31-35 (“The plurality of separate electrodes are independently and sequentially energized and controlled with thermistor temperature feedback control to bring the [tissue] temperature to a desired level.”). Overall, using bipolar pairs, like those taught by Stern, to direct such energy means that the clinician (or an automated system) can target small, specific areas of tissue and adjust the treatment as necessary.

66. ***Third***, another advantage of bipolar electrode pairs is that they lead to more precise and even heating. For example, Stern explains that “it would be more precise to provide a more even heating of a uterus or other body organ if the electrode could have a controlled return path for the current.” Ex.1009-Stern, 12:25-27. As I explained in Section VI.B (Monopolar and Bipolar RF Electrode Configurations) in relation to the differences between monopolar and bipolar electrodes, using bipolar RF energy allows a user to control the return path because the electrical current flows

only between the active and return electrodes, which are placed inside of the body. As I explained, this can be a safer option for the patient, especially when performing ablation in the head. This precision and even heating is also exactly what Saadat's technique calls for—i.e., Saadat seeks to ablate tissue in the nasal cavity to treat rhinitis (*see, e.g.*, Ex.1003-Saadat, 30:36-42, 31:10-19), which requires precision and control of heating on a local level to account for variations.

67. A person of ordinary skill in the art would have relied on Stern's advantages as teachings, suggestions, and motivations to modify Saadat in view of Stern to include those advantages in Saadat's RF ablation probe. Doing so would have involved using Stern's known bipolar pairing technique to fill in details of Saadat, which would have been desirable for increased safety and control. Increased safety would have been a predictable result from this combination, as increased control and even tissue heating would avoid unwanted ablation of adjacent tissue and over-heating of target tissue (as discussed in this section).

68. Stern's bipolar pairing technique would have also improved Saadat's similar device in a similar way because it would have led to advantages for Saadat's device. A person of ordinary skill in the art also would have been motivated to combine Saadat and Stern because Saadat's known device was ready for improvement (given that Saadat leaves to a POSITA how to pair and wire the

electrodes). As detailed above, it would have been apparent to a person of ordinary skill in the art that Stern's electrodes, which have the advantages of, for example, pairing, safety, and control, would have readily achieved Saadat's stated goal of ablating tissue in the nasal cavity to treat rhinitis. *E.g.*, Ex.1003-Saadat, 1:21-26, 3:6-14, 10:16-11:14, 30:36-42, 31:10-19.

69. The Saadat and Stern references describe very similar objectives, devices, and techniques for delivering bipolar RF ablation energy. For example, both disclose bipolar RF electrodes and discuss delivering RF energy to tissue. *See, e.g.*, Ex.1003-Saadat, Abstract, 1:21-26, 3:6-14, 10:16-11:14, 30:36-42, 31:10-19; Ex.1009-Stern, 1:16-43, 7:38-8:38, 10:48-65.

70. These similarities would have led a person of ordinary skill in the art to expect that applying the teachings from Stern to the device of Saadat would have been straightforward and would have yielded predictable results. Based on my experience developing ablation devices during the relevant time period, my knowledge of the level of skill in the art at that time, and the disclosure of the references themselves, I believe a person of ordinary skill in the art would have would have had a reasonable expectation of success at configuring the bipolar RF electrodes in Saadat's RF ablation probe in multiple pairs as taught by Stern. As I noted above, Saadat leaves its electrode arrangement and control technique to the

knowledge of skilled artisans. *E.g.*, Ex.1003-Saadat, 30:41-47. Consistent with my recollection from the relevant time period, Saadat recognized that it was well within a person of ordinary skill in the art's skill to implement a system that independently delivers RF energy to different bipolar electrodes using, for example, the wiring of Stern. *See, e.g.*, Ex.1003-Saadat, 30:41-47. Doing so would have merely involved the use of a standard switching apparatus as well as routine implementation of software that selectively controls such switches.

71. Moreover, in the combination, Stern's known techniques would have been used to improve Saadat's similar device in the same way. For example, Saadat describes an RF ablation probe for delivering RF energy to a body cavity, Ex.1003-Saadat, Abstract, 1:21-26, 3:6-14, 10:16-11:14, 30:36-42, 31:10-19, Figs.20E, 30, and Stern discloses a way to pair such bipolar surface RF electrodes on an expandable device and wire such electrodes for independent energy delivery, Ex.1009-Stern, FIGs.15, 19, 2:49-53, 12:38-13:55. Stern's teachings would have been applied to Saadat in the same way they are used in Stern.

72. Moreover, POSITAs routinely considered techniques and technology from ablation devices suitable for treating one area of the body applicable to devices in another area of the body. When developing an ablation device, persons of skill in the art would not have reinvented the wheel—instead they would have looked to

existing ablation technology to identify relevant and useful teachings, and expected success in doing so. Stern expressly notes the applicability of its disclosure to other parts of the body:

One of the more obvious variations based upon the above disclosure is the utilization of such an electrode partitioning structure and the accompanying heating for treatment of other body organs or tissues either externally or internally. The principles embodied herein and the methods utilizing those principles with respect to the delivery of controlled RF energy in a controlled environment have application in many areas, not only for controlled destruction of tissue but also for controlled heat treatment of tissue. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

Ex.1009-Stern, 18:27-40.

73. Accordingly, applying Stern's teachings to Saadat would have been a matter of routine implementation within the skill of a person of ordinary skill in the art that would have yielded predictable successful results. In other words, a POSITA would have had a reasonable expectation of success at energizing the multiple bipolar electrodes on Saadat's RF ablation probe as Stern teaches because doing so was a matter of routine implementation within the skill of a person of ordinary skill in the art that would have yielded predictable successful results.

74. A person of skill in the art would have reasonably expected success when implementing *multiple pairs of bipolar radiofrequency electrodes* in Saadat's RF ablation probe. As I explained above in this section, Saadat teaches an RF

ablation probe with multiple bipolar electrodes, and teaches that “[t]hose skilled in the art of RF ablation probes are familiar with the many possible configurations and construction techniques for RF electrodes and probes that are within the scope of this invention....” Ex.1003-Saadat, 30:34-47, 31:10-19, 33:41-49. Thus, Saadat teaches and confirms that other aspects of electrode arrangement and control would have been within the skillset of those of ordinary skill. Stern specifically teaches that its multiple pairs of bipolar electrodes “have application in many areas, not only for controlled destruction of tissue but also for controlled heat treatment of tissue” (i.e., RF ablation). Ex.1009-Stern, 18:27-40. Additionally, the ’077 patent itself assumes (correctly) that a POSITA would have understood how to implement multiple pairs of bipolar electrodes. The ’077 patent generically references multiple pairs of electrodes without providing any implementation details. *See* Ex.1001-USP077, 18:37-46.

75. Implementing Stern’s multiple pairs of bipolar electrodes into Saadat’s RF ablation device would have involved combining known prior art elements (Saadat’s RF ablation probe with multiple bipolar RF electrodes) with known methods (e.g., Stern’s selective control techniques) to yield predictable results (fine-tuned energy delivery and control). In other words, implementing Stern’s multiple bipolar electrodes in Saadat’s RF ablation provide would have been routine and

involved using one known feature, Stern's multiple pairs of bipolar electrodes, with another, Saadat's multiple bipolar electrodes, to obtain the predictable result of finer control of RF energy delivery and temperature control. Indeed, using Stern's individual bipolar electrode control and arrangement would have also improved the similar Saadat's RF ablation probe in a similar way, namely by providing finer granularity for control of energy, and therefore more precise temperature control/maintenance. Saadat's RF ablation device was ready for such improvement, since Saadat left electrode arrangement/control details to the discretion of a person of skill in the art.

76. Thus, it is my opinion that a POSITA would have had a reasonable expectation of success at implementing Stern's multiple pairs of bipolar electrodes into Saadat's RF ablation device. Indeed, it is my opinion that this implementation was well within the skillset of a POSITA would be the predictable result of using one known feature with another to reach predictable results.

77. In conclusion, it is my opinion that a POSITA would have been motivated to combine the teachings of Saadat and Stern with a reasonable expectation of success.

B. Ground VI: Claim 4 In view of the Combination of Makower, Fang, Edwards-535, and Stern

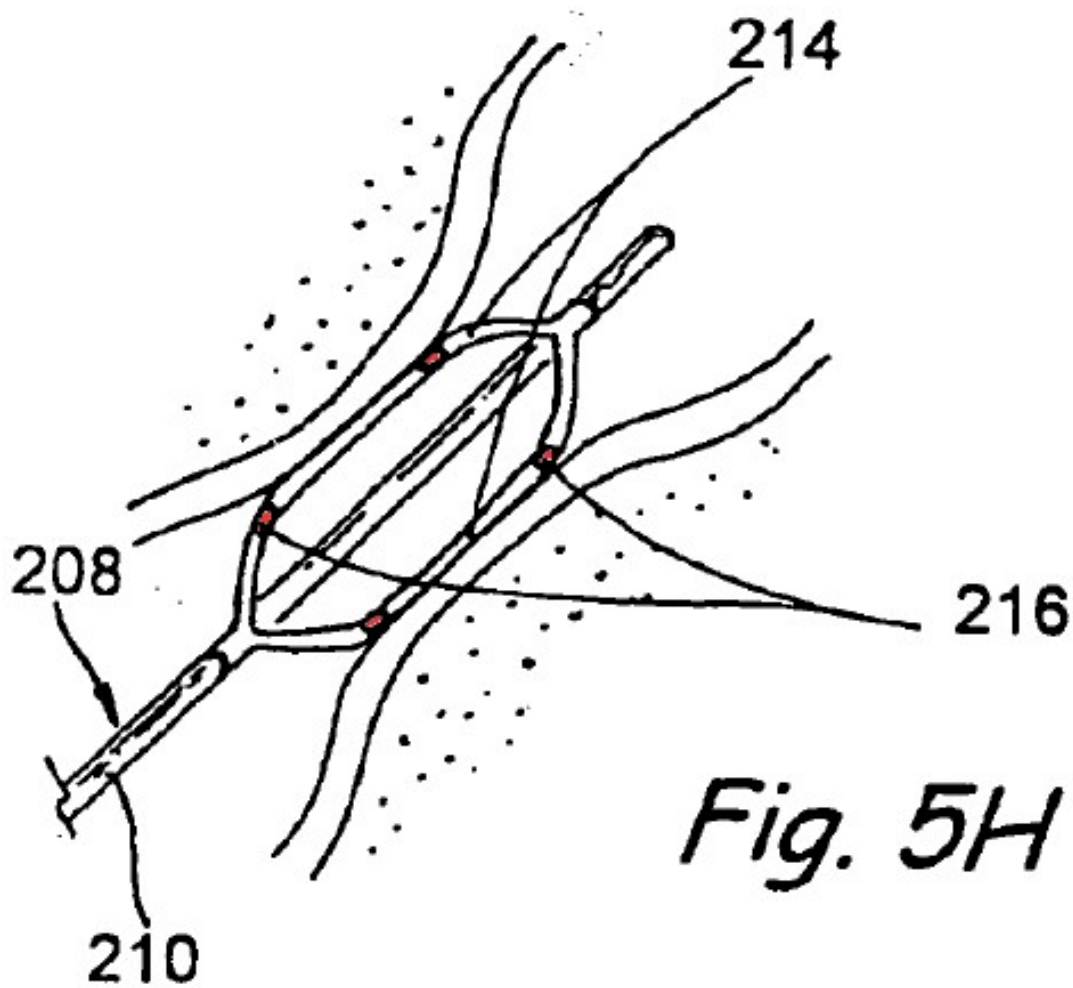
78. Claim 4 recites the following: “The apparatus of claim 2, wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.” As detailed below, it is my opinion that a POSITA would have been motivated to combine the teachings of Makower, Fang, Edwards-535, and Stern with a reasonable expectation of success.

1. Makower

79. Makower teaches “medical devices and methods and more particularly...minimally invasive, catheter based devices, systems and methods for treating sinusitis and other ear, nose & throat disorders.” Ex.1005-Makower, [0001], [0043], [0160]-[0161], [0164], [0187], FIG.5H.

80. One of Makower’s disclosed devices is shown in Figure 5H (below). Figure 5H “shows an electrosurgical device 208 comprising a flexible shaft 210 (e.g., a catheter or solid shaft) having arched strut members 214 attached thereto.” Ex.1005-Makwer, [0187]. Makower teaches that “[e]lectrodes 216 are located on the strut members 214,” and are **bipolar RF electrodes**. *Id.*; *see also id.*, [0164] (“[T]he working devices shown in FIGS. 5A-5Y” and described herein incorporate assemblies, components or mechanisms (e.g.,...radiofrequency electrodes[]).”),

[0187] (“The **electrodes 216** may be bipolar, monopolar or facilitated by any other suitable form of energy....”).



Ex.1005-Makower, FIG.5H.

81. Makower also teaches that the electrosurgical device is “inserted into the nasal cavity” or “nasopharynx...to perform diagnostic or therapeutic procedures.” Ex.1005-Makower, [0161]; *see also id.*, [0043] (“In accordance with the present invention, there are provided methods wherein one or more flexible

catheters or other flexible elongate devices as described herein are inserted [into] the nose, nasopharynx, paranasal sinus, middle ear or associated anatomical passageways to perform an interventional or surgical procedure.”). Makower explains that after the device is positioned proximate to tissue, “current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.” *Id.*, [0187].

82. Although Makower teaches an electrosurgical device with multiple RF bipolar electrodes, Makower does not teach specific implementation details for its multiple RF bipolar electrodes. *See, e.g.*, Ex.1005-Makower, [0161], [0164], [0187]. Instead, Makower explains that the “designs and constructions of such components and assemblies are w[e]ll known in the art.” *Id.*, [0164].

2. Fang

83. Fang teaches using radiofrequency to treat rhinitis. Ex.1006-Fang, 876-877. In particular, Fang teaches using “the SHP-I five-organ radiofrequency therapy instrument (manufactured by Guangzhou Medical Instrument Factory)...with the Level 3 intensity selected,” and aligning “the firing head...with the sphenopalatine foramen on both sides, to carry out radiofrequency at the anterior upper part of the nasal septum on both sides....” *Id.*, 876. Fang teaches that “[t]he use of radiofrequency technique completely blocks the parasympathetic pathway of the

nasal mucosa,” which “reduces glandular secretion, and thus achieves the therapeutic purposes.” *Id.*, 877.

84. Although Fang discloses using radiofrequency to treat tissue, Fang does not disclose that a specialized device is necessary to perform radiofrequency ablation and does not disclose specific implementation details for radiofrequency electrodes. Ex.1005-Fang, 876-877.

3. Edwards-535

85. Edwards-535 teaches “[a]n apparatus...for ablating at least a portion of a nasal concha.” Ex.1008-Edwards-535, Abstract. Edwards-535 explains that the nasal concha may also be called “turbinates.” *Id.*, 1:63-66.

86. In particular, Figure 6 of Edwards-535 teaches an “apparatus 124 [that] includes a catheter body 126 which has a distal portion 128 with dimensions configured for introduction through a nostril of a patient into a nasal meatus of a patient.” Ex.1008-Edwards-535, 7:28-32, 8:17-25. Edwards-535 explains that “[a]n expandable member 132 is attached to the catheter body 126 at the catheter distal portion 128,” and “[a]lso attached to the catheter body 126 at the catheter distal portion 128 is an energy delivery device 134 for delivering ablative energy.” *Id.*, 7:33-36. As shown in Figure 6, Edwards-535’s “energy delivery device includes

one or more ring electrodes 156 disposed on the surface of the expandable member 132.” *Id.*, 8:17-25.

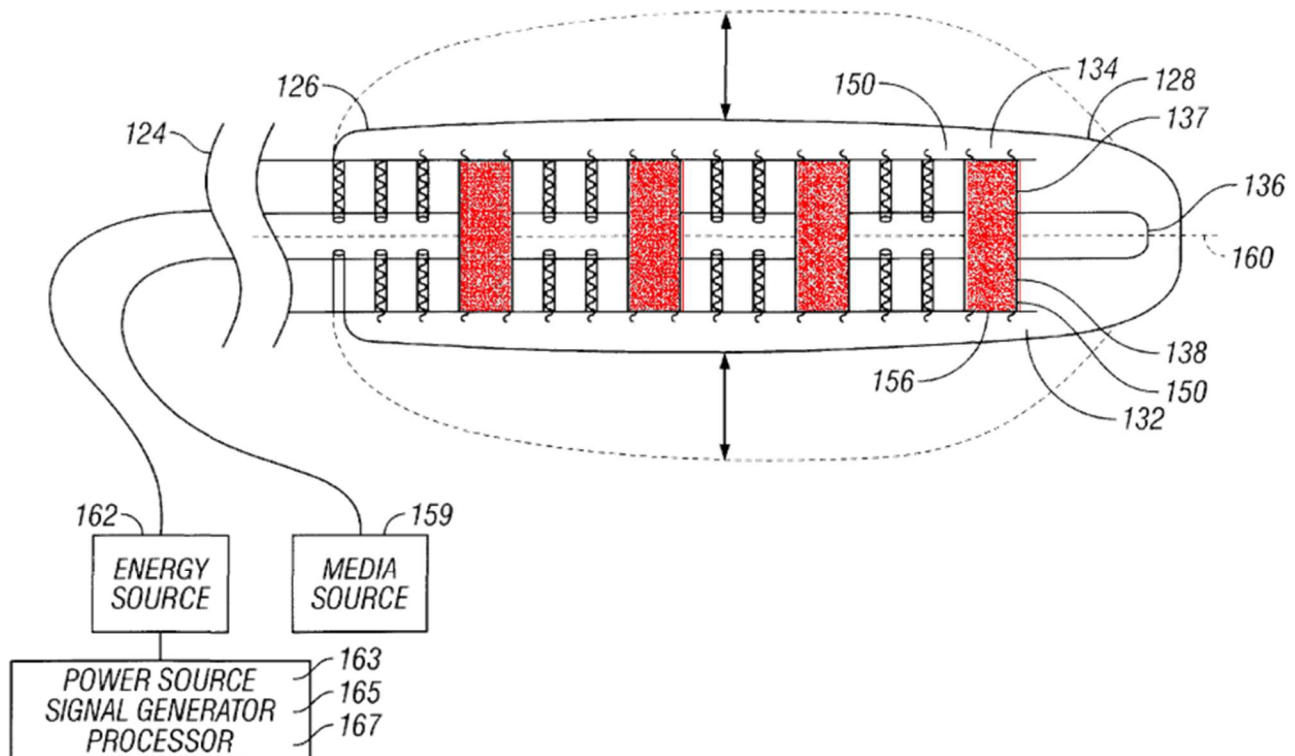


FIG. 6

Ex.1008-Edwards-535, FIG.6. Edwards-535 further teaches that “ablative energy is supplied to the energy delivery device by an energy source 162,” which “includes an energy source 163 (or a power regulator coupled to a standard energy source such as a wall socket or battery), a signal generator 165 (such as a generator for pulses, sine waves, square waves, or some combination of these wave forms with each other or with some other wave form), and a processor 167 for controlling the signal generator.” *Id.*, 8:46-60. Edwards-535 explains that its ablative energy is RF

energy, and as one example, explains that “the signal generator can generate pulses of RF energy which provide between about 5 and about 30 watts of RF energy” to tissue. *Id.*, 8:46-53, 9:8-13, 11:46-12:4.

87. Edwards-535 also provides an example of energy in the MHz (megahertz) range, as it teaches that its “the signal generator generates pulses of RF energy having an RF radiation frequency between about 300 megahertz and about 700 megahertz, such as preferably about 465 megahertz.” Ex.1008-Edwards-535, 8:61-67. In the early 2000s, most RF ablation devices for various body tissues operated at a frequency in the kHz (kilohertz) range, including between 300 and 700 kilohertz. *See, e.g.,* Ex.1066-Edwards-886, 36:66-37:7 (“In the illustrated embodiment, the integrated generator 38 has four independent radio frequency channels. Each channel is capable of supplying up to 15 watts of radio frequency energy with a sinusoidal waveform at 460 kHz.”); Ex.1056-Sackenheim, 90 (explaining that three companies that manufactured RF ablation generators in the United States used either 460kHz or 480kHz generators); Ex.1067-Bronzino, 63-4 (teaching that a typical bipolar mode frequency range for an electrosurgical device is between 300kHz and 1050kHz). A POSITA would have been well aware of this range and would have understood that the MHz range in Edwards-535 may contain a typographical error that should have referred to the more commonly used kHz

range. Whether or not this statement is a typographical error, the inclusion of this range does not change my opinions in this declaration, including because Edwards-535 teaches, consistent with my experience, that a person of ordinary skill in the art could—and it would have been obvious to—adjust a radiofrequency generator to a desired range for RF ablation as a matter well within their skill (e.g., to a kHz range that is more typical for ablation than a MHz range). *See* Ex.1008-Edwards-535, 11:46-12:4.

88. Although Edwards-535 teaches delivering energy to an RF ablation probe with multiple RF electrodes using a generator, Edwards-535 does not disclose specific details for its multiple RF electrodes. *See* Ex.1008-Edwards-535, 11:46-12:4 (“[I]t is contemplated that modifications will readily occur to those skilled in the art....”).

4. Stern

89. As I explained in Section IX.A.2 (Ground III, Claim 4, Stern), Stern teaches *two bipolar radiofrequency electrodes that comprise multiple pairs of bipolar radiofrequency electrodes*

5. Motivation to Combine with a Reasonable Expectation of Success

90. As I explained in Section III.C (Legal Principles – Obviousness), I have been informed by Petitioners’ counsel and understand that for a claim to be obvious,

a POSITA must have had a reason or motivation to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so. It is my opinion that a POSITA would have been motivated to combine the teachings of Makower, Fang, Edwards-535, and Stern with a reasonable expectation of success.

91. In my opinion, a person of ordinary skill in the art would have been motivated to incorporate Stern's teaching regarding at least two rows of bipolar electrode pairs into the device in Makower for several reasons.

92. Makower discloses delivering RF energy to tissue using bipolar RF electrodes, but does not provide details regarding how to configure its bipolar electrodes. Similarly, Fang and Edwards-535 each teach applying RF energy to tissue and Edwards-535 teaches an RF generator for supplying RF energy to multiple electrodes, but each reference also does not provide details regarding how to configure RF electrodes. A person of ordinary skill in the art would have been motivated to incorporate the teachings from Stern when implementing the device taught by the combination of Makower, Fang, and Edwards-535 because it provides detailed information and schematics regarding how to design an RF ablation device with surface electrodes so the electrodes deliver bipolar RF energy and can deliver energy independently through the different electrodes. Stern teaches that its bipolar

electrode configuration provides a number of benefits, including providing even heating and precise energy delivery control that are particularly beneficial when trying to ablate an uneven surface.

93. Makower exemplifies that using RF ablation devices with multiple bipolar surface electrodes in body cavities was well-known. Makower specifically teaches “an electrosurgical device” with multiple “bipolar” RF electrodes on struts that apply current to tissue to “caus[e] tissue adjacent to the struts 214 to be cauterized or heated.” *See* Ex.1005-Makower, [0161], [0164], [0187]. Fang and Edwards-535 similarly exemplify that applying RF energy to tissue was well-known, as each reference teaches using RF energy to treat tissue. *See* Ex.1006-Fang, 876-877; Ex.1008-Edwards-535, 7:28-36, 8:17-25, 8:46-53. And Edwards-535 exemplifies using an RF generator to operate such electrodes. *E.g.*, Ex.1008-Edwards-535, 7:28-36, 8:17-25. While a person of ordinary skill in the art would have understood that implementation of bipolar electrodes was routine, Makower, Fang, and Edwards-535 do not provide details on how to implement such energy delivery, leaving it to the skill of a person of ordinary skill in the art. *See, e.g.*, Ex.1005-Makower, [0164] (“The designs and constructions of such components and assemblies are w[e]ll known in the art.”). A person of skill in the art would have used Stern’s scheme to implement Makower’s multiple bipolar electrodes, because

Stern provides very detailed schematics and information about how to design a device that can accomplish this goal.

94. It would have been within the skill of a person of ordinary skill in the art to implement the energy delivery taught by Makower, and such a POSITA would have been motivated to turn to other sources for that information, including regarding how to implement independent energy delivery through each electrode for bipolar energy delivery. As I explained in Section IX.A.2 (Ground III, Claim 4, Stern) and Section IX.A.3 (Ground III, Claim 4, Motivation to Combine with a Reasonable Expectation of Success), when faced with how to independently deliver energy to each electrode or electrode pair, a person having ordinary skill in the art would have had only a limited number of choices. Specifically, a person of skill in the art would have had to choose whether to use multiple RF generators or just a single RF generator. If using multiple RF generators, electrodes would be individually wired to each generator. If using a single RF generator, circuitry would have been required to control the route of energy (taught by Stern), which could be implemented by switches or relays. A person having ordinary skill in the art would have been motivated to use only one RF generator, as was common at the time. *E.g.*, Ex.1008-Edwards-535, FIGs.5-6, 8:46-60. Further, a system incorporating only one voltage source is safer (e.g., there are fewer components and more consistency in

output for each bipolar pair), more practical (e.g., it would be impractical to use multiple generators when one would suffice, and multiple generators would take up more space in the device), and more reliable (e.g., there would be fewer complex generators that could fail and cause the entire device to be inoperative by virtue of one pair not being useable) than one with numerous power sources. Switches or relays also take up less space than multiple generators, and would have been simpler and cheaper than multiple complex voltage sources.

95. As I also explained in Section IX.A.2 (Ground III, Claim 4, Stern) and Section IX.A.3 (Ground III, Claim 4, Motivation to Combine with a Reasonable Expectation of Success), a person of ordinary skill in the art would have been motivated to refer to Stern because it provides detailed information regarding how to design and wire a device that provides RF energy to electrodes independently with a single voltage source such as the energy source taught by Edwards-535. *E.g.*, Ex.1008-Edwards-535, FIGs.5-6, 8:46-60. Stern's Figures 5 and 15 provide detailed electrical schematics showing how to wire and control various sensors and electrodes in a bipolar arrangement. For example, Figure 5 of Stern shows multiple electrodes 50 connected to a switch bank for independent energy delivery, as well as a temperature measurement circuitry including switch bank 52 for each respective electrode. Ex.1009-Stern, 9:2-24, FIG.5. Likewise, Figure 15 shows a flexible

circuit that can be used to provide power from a voltage source 228 to any pair of electrodes in the array 220, 222, 224, and 226 for bipolar RF energy application. *Id.*, 12:38-13:2, FIG.15. Stern also provides specific details regarding how to manufacture and arrange electrodes on the surface of an expandable bladder, an example of which is shown in Figure 19. *Id.*, 14:8-60, FIG.19.

96. Further, a person of ordinary skill in the art would have also been motivated to improve Saadat's RF ablation device by configuring Saadat's multiple bipolar RF electrodes in pairs as taught by Stern based on the advantages and benefits of Stern's design, as disclosed in Stern. As I explained in Section IX.A.2 (Ground III, Claim 4, Stern) and Section IX.A.3 (Ground III, Claim 4, Motivation to Combine with a Reasonable Expectation of Success), Stern teaches that pairing bipolar electrodes provides a number of advantages and benefits including: (1) bipolar RF electrode pairs allow a user to precisely control the electrical current delivered to tissue, which in turn provides for control of the area being heated; (2) bipolar RF electrode pairs allow a physician to target specific tissue while minimizing the chance that tissue that is not being targeted is affected (e.g., not heated and remaining unchanged); and (3) bipolar RF electrode pairs provide more precise and even heating.

97. A person of ordinary skill in the art would have relied on Stern's advantages as teachings, suggestions, and motivations to modify the combination of Makower, Fang, and Edwards-535 in view of Stern to include those advantages in Makower's electrosurgical device. Doing so would have involved using Stern's known bipolar pairing technique to fill in details of Makower, Fang, and Edwards-535, which would have been desirable for increased safety and control. Increased safety would have been a predictable result from this combination, as increased control and even tissue heating would avoid unwanted ablation of adjacent tissue and over-heating of target tissue (as discussed in this section, Section IX.A.2 (Ground III, Claim 4, Stern), and Section IX.A.3 (Ground III, Claim 4, Motivation to Combine with a Reasonable Expectation of Success)).

98. A person of ordinary skill in the art also would have been motivated to combine Makower, Fang, Edwards-535, and Stern because Makower's known device was ready for improvement (given that Makower leaves to a POSITA how to pair and wire the electrodes). As detailed above, it would have been apparent to a person of ordinary skill in the art that Stern's electrodes, which have the advantages of, for example, pairing, safety, and control, would have readily achieved Makower's stated goal of ablating tissue in the nasal cavity or nasopharynx to treat a nasal condition. *E.g.*, Ex.1005-Makower, [0043].

99. Makower and Stern describe similar objectives, devices, and techniques for delivering bipolar RF ablation energy. For example, both disclose bipolar RF electrodes and discuss delivering RF energy to tissue. *See, e.g.*, Ex.1005-Makower, Abstract, [0001], [0043], [0161], [0164], [0187]; Ex.1009-Stern, 1:16-43, 7:38-8:38, 10:48-65. Similarly, Fang and Stern describe similar objectives, devices, and techniques for delivering RF energy, as each both disclose treating tissue with RF energy. *E.g.*, Ex.1006-Fang, 876-877; Ex.1009-Stern, 1:16-43, 2:6-19. And Edwards-535 and Stern also describe similar objectives, devices, and techniques for delivering RF energy to tissue via an energy source. *E.g.*, Ex.1008-Edwards-535, 7:28-36, 8:47-60; Ex.1009-Stern, 12:46-13:2.

100. These similarities would have led a person of ordinary skill in the art to expect that applying the teachings from Stern to the device of Makower would have been straightforward and would have yielded predictable results. Based on my experience developing ablation devices during the relevant time period, my knowledge of the level of skill in the art at that time, and the disclosure of the references themselves, it is my opinion that a person of ordinary skill in the art would have would have had a reasonable expectation of success at configuring the bipolar RF electrodes in Makower's electrosurgical device in multiple pairs as taught by Stern. As I noted above, Makower leaves its electrode arrangement and control

technique to the knowledge of skilled artisans. *E.g.*, Ex.1005, Makower, [0164], [0187]. Consistent with my recollection from the relevant time period, Makower recognized that it was well within a person of ordinary skill in the art's skill to implement a system that independently delivers RF energy to different bipolar electrodes using, for example, the wiring of Stern. *E.g.*, Ex.1005-Makower, [0164]. Doing so would have merely involved the use of a standard switching apparatus as well as routine implementation of software that selectively controls such switches.

101. Additionally, a person of ordinary skill in the art would have expected that combining pairs of bipolar electrodes as taught by Stern with an energy source as taught by Edwards-535 would have been successful, straightforward, and would have yielded predictable results. Based on my experience developing ablation devices during the relevant time period, my knowledge of the level of skill in the art at that time, and the disclosure of the references themselves, it is my opinion that a person of ordinary skill in the art would have had a reasonable expectation of success at using an energy source as taught by Edwards-535 with Stern's electrode configuration implementation in Makower. Indeed, use of such configurable power source would have been a typical part of the basic operation of electrodes like those taught by Stern. As discussed in this section, Edwards-535, like Makower, recognized that it was well within the skillset of a person of ordinary skill in the art

to implement a system that independently delivers RF energy from an energy source to different bipolar electrodes using, for example, the wiring of Stern. *E.g.*, Ex.1008-Edwards-535, 8:17-24, 11:46-12:4. Implementing Stern's electrode configuration with an energy source as taught by Edwards-535 would also have merely involved the use of a standard switching apparatus as well as routine implementation of software that selectively controls such switches.

102. Moreover, in the combination, Stern's known techniques would have been used to improve Makower's similar device in the same way Stern teaches. For example, Makower describes an RF ablation probe for delivering RF energy to a body cavity, Ex.1005, Makower, [0001], [0043], [0161], [0164], [0187], Fig.5H, and Stern discloses a way to pair such bipolar surface RF electrodes on an expandable device and wire such electrodes for independent energy delivery, Ex.1009-Stern, FIGs.15, 19, 2:49-53, 12:38-13:55. Stern's teachings would have been applied to Makower in the same way they are used in Stern.

103. Moreover, as I explained in Section IX.A.2 (Ground III, Claim 4, Stern) and Section IX.A.3 (Ground III, Claim 4, Motivation to Combine with a Reasonable Expectation of Success), POSITAs routinely considered techniques and technology from ablation devices suitable for treating one area of the body applicable to devices in another area of the body. When developing an ablation device, persons of skill in

the art would not have reinvented the wheel—instead they would have looked to existing ablation technology to identify relevant and useful teachings, and expected success in doing so. Stern expressly notes the applicability of its disclosure to other parts of the body:

One of the more obvious variations based upon the above disclosure is the utilization of such an electrode partitioning structure and the accompanying heating for treatment of other body organs or tissues either externally or internally. The principles embodied herein and the methods utilizing those principles with respect to the delivery of controlled RF energy in a controlled environment have application in many areas, not only for controlled destruction of tissue but also for controlled heat treatment of tissue. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

Ex.1009-Stern, 18:27-40.

104. Accordingly, applying Stern's teachings to the combination of Makower, Fang, and Edwards-535 would have been a matter of routine implementation within the skill of a person of ordinary skill in the art that would have yielded predictable successful results. In other words, a POSITA would have had a reasonable expectation of success at energizing the multiple bipolar electrodes on Makower's electrosurgical device using an energy source as taught by Edwards-535, as Stern teaches because doing so was a matter of routine implementation within the skill of a person of ordinary skill in the art that would have yielded predictable successful results.

105. A person of skill in the art would have reasonably expected success when implementing *multiple pairs of bipolar radiofrequency electrodes* in Makower's electrosurgical device. As I explained above in this section, Makower teaches an electrosurgical device with multiple bipolar electrodes, and teaches that "designs and constructions of such components and assemblies are w[e]ll known in the art." *E.g.*, Ex.1005-Makower, [0161], [0164, [0187]. Fang and Edwards-535 also teach applying RF energy and Edwards-535 teaches an RF generator, but each reference does not provide detailed information on how to configure RF electrodes. Thus, Makower, Fang, and Edwards-535 teach and confirm that other aspects of electrode arrangement and control would have been within the skillset of those of ordinary skill. Stern specifically teaches that its multiple pairs of bipolar electrodes "have application in many areas, not only for controlled destruction of tissue but also for controlled heat treatment of tissue" (i.e., RF ablation). Ex.1009-Stern, 18:27-40. Additionally, as I explained in Section IX.A.2 (Ground III, Claim 4, Stern) and Section IX.A.3 (Ground III, Claim 4, Motivation to Combine with a Reasonable Expectation of Success), the '077 patent itself assumes (correctly) that a POSITA would have understood how to implement multiple pairs of bipolar electrodes. The '077 patent generically references multiple pairs of electrodes with providing any implementation details. *See* Ex.1001-USP077, 18:37-46.

106. Implementing Stern's multiple pairs of bipolar electrodes into Makower's RF ablation device would have involved combining known prior art elements (Makower's electrosurgical device with multiple bipolar RF electrodes) with known methods (e.g., Stern's selective control techniques) to yield predictable results (fine-tuned energy delivery and control). In other words, implementing Stern's multiple bipolar electrodes in Makower's electrosurgical device using an energy source as taught by Edwards-535 would have been routine and involved using one known feature, Stern's multiple pairs of bipolar electrodes, with another, Makower's multiple bipolar electrodes using an energy source as taught by Edwards-535, to obtain the predictable result of finer control of RF energy delivery and temperature control. Indeed, using Stern's individual bipolar electrode control and arrangement would have also improved the similar Makower's electrosurgical device in a similar way, namely by providing finer granularity for control of energy, and therefore more precise temperature control/maintenance. Makower's electrosurgical device was ready for such improvement, since Makower left electrode arrangement/control details to the discretion of a person of skill in the art.

107. Thus, it is my opinion that a POSITA would have had a reasonable expectation of success at implementing Stern's multiple pairs of bipolar electrodes into Makower's electrosurgical device. Indeed, it is my opinion that this

implementation was well within the skillset of a POSITA would be the predictable result of using one known feature with another to reach predictable results.

108. In conclusion, it is my opinion that a POSITA would have been motivated to combine the teachings of Makower, Fang, Edwards-535, and Stern with a reasonable expectation of success.

X. AVAILABILITY FOR CROSS-EXAMINATION

109. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

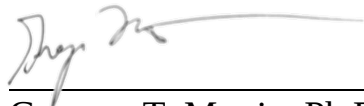
XI. RIGHT TO SUPPLEMENT

110. I reserve the right to supplement my opinions in the future to respond to any arguments that Patentee raises and to take into account new information as it becomes available to me.

XII. JURAT

111. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: January 15, 2024

A handwritten signature in dark ink, appearing to read "Gregory T. Martin", is written over a horizontal line.

Gregory T. Martin, Ph.D.

APPENDIX A

Gregory T. Martin, Ph.D.

2 Shipway Place, Boston, MA 02129 USA, +1-617-429-3911, greg.martin@tremontconsult.com

Summary:

Dr. Martin is an executive, entrepreneur, engineer and scientist with 25 years of experience developing products, commercializing medical technologies and building successful businesses in start-ups and publicly-traded corporations. He has a track record of success in executive management, team building, change/crisis management, business development, strategic partnerships, product launch, marketing, operations, program management, product development, R&D, clinical research, and regulatory affairs.

Professional Experience:

Tremont Consulting, LLC

Principal

Boston, MA

2012-2013, 2018-present

Provide consulting services on a variety of topics to the medical device and diagnostics industry including strategy, fund raising, opportunity analysis, due diligence, regulatory strategy, program/portfolio management, product development, technology development, R&D, grant writing and expert witness testimony (patent & product liability). Clients include startups, corporations, law firms and investment firms.

- Recent engagements include surgical robotics, infectious disease diagnostics & therapies (including SARS-CoV-2 and sepsis), endoscopy, neurodegenerative disease, neuro-oncology, neurovascular devices, laparoscopic surgery, tissue ablation, ICU monitoring, transdermal drug delivery, & women's health.
- Can act as a stand-in CTO/COO, team mentor and Entrepreneur in Residence.

Boston University, Department of Biomedical Engineering

Senior Lecturer (part time)

Boston, MA

2019-2020

- Course Director and Instructor for BE695: Advanced Biomedical Design & Development (graduate)

Opsonix, Inc.

Vice President of Research and Development

Wakefield, MA

2017- 2018

Developed a device-biologic combination product and companion diagnostic to remove pathogens and endotoxins from blood via an extracorporeal circuit to treat sepsis. Opsonix was spun out of the Harvard Wyss Institute with \$9 million investment from Baxter Ventures and Hansjörg Wyss.

Responsibilities

- Led the product development, design verification and preclinical studies
- Provided periodic technical updates to the BOD
- Identified and engaged clinical sites

Accomplishments

- Implemented a cloud-based design control and PLM system in compliance with FDA QSR
- Directly interfaced with the FDA via 4 presubmission meetings & associated interactions
- Obtained FDA IDE approval for a first in human clinical study with 15 patients, January 2018

Boston University, Department of Biomedical Engineering

Senior Lecturer and Director of the Coulter Translational Research Program

Boston, MA

2013 – 2017

Led a Coulter Foundation program to translate medical device & diagnostics to commercialization.

Responsibilities

- Solicited & evaluated grants, selected awardees, mentored investigators, & managed progress
- Instructor for BE467: Product Design & Innovation in Biomedical Engineering (undergraduate)
- Instructor for BE695: Advanced Biomedical Design and Development (graduate)
- Instructor for Health Care Entrepreneurship for BU medical students at the School of Business

Accomplishments

- Deployed approximately \$1 million each year to provide gap funding for technology translation
- Facilitated the formation of 3 startup companies with the Office of Technology Development
- Created and delivered a seminar series on medical device commercialization to the faculty
- Taught medical device product development to over 300 students in total

Hologic, Inc. (NASDAQ: HOLX)

Marlborough, MA

Vice President of Research and Development

2007- 2011

A leading women's health company with specialization in laboratory diagnostics, digital mammography, bone densitometry and minimally invasive surgical devices with annual revenue of over \$1.7 billion. Responsible for R&D in the Surgical Products Division for all released and new products. The released products account for approximately \$300 million in annual revenue.

Accomplishments

- Led the release of the next generation products (capital equipment with software and invasive surgical devices) which increased divisional revenue and significantly improved product quality
- Conceived, initiated and led numerous R&D and new product development projects
- Expanded the research and product development pipeline to include organic innovation
- Partnered with development/start-up companies to expand technology and product portfolio
- Key member of senior management team that grew annual divisional revenue to \$300 million
- Key member of the deal team for the \$352 million acquisition of Interlace Medical, Inc.
- Led technical due diligence for numerous potential acquisition candidates.
- Created a program management function to manage product portfolio and development
- Integrated the R&D functions from acquisition sites into the Marlborough facility

Responsibilities

- Managed approximately 45 direct and indirect reports within the R&D department
- Directly/indirectly guided over 100 people in matrix functions that supported R&D programs
- Managed relationship with off-shore high volume manufacturing facility
- Provided mentoring and oversight for manufacturing engineering and process development
- Key member of senior management team that formulated divisional strategy and set goals
- Formulated and implemented R&D and product development strategy
- Set division and departmental goals and priorities related to R&D
- Provided periodic updates to the Board of Directors
- Ensured the department achieved annual goals and budget targets
- Directly interfaced with FDA to support applications/amendments for PMA Class 3 devices
- Reported to the division general manager

Cytec Corporation (NASDAQ: CYTC)

Marlborough, MA

Vice President of Research and Development

2007

A leader in women's health with annual revenue of \$700 million. Responsible for R&D in the medical device (Cytec Surgical Products) division for all released and new products. CSP marketed world-class products to treat menorrhagia (NovaSure®), breast cancer with radiotherapy (MammoSite®), and brain cancer with radiotherapy (GliaSite®). Cytec merged with Hologic in October 2007.

Accomplishments

- Created and lead the divisional R&D department at corporate headquarters
- Led the transition of the R&D department from California to Massachusetts
- Built an outstanding medical device R&D department, hired entire department staff
- Created an entrepreneurial environment to enhance innovation
- Led technical due diligence for acquisitions, venture investments & development agreements
- Key member of the deal team for the \$215 million acquisition of Aadiana
- Led the integration of R&D facilities, resources and programs obtained via acquisition
- Created close cross functional collaboration with Marketing, Sales, and Operations

Responsibilities

- Managed R&D at 3 national sites
- Created and managed product pipeline/portfolio
- Formulated research and product development plans, and budgets
- Set division and departmental goals and priorities related to R&D
- Responsible for ensuring that R&D achieved annual goals and budget targets
- Managed development agreements with partner start-up companies
- Reported to the division president

Hemedex, Inc.

Cambridge, MA

Co-founder, Chief Technology Officer and Corporate Director

2000-2007

A medical device start-up that developed and commercialized a device to monitor cerebral blood flow at the bedside in neurosurgery patients with traumatic brain injury, cerebro-vascular disease and stroke. Responsible for R&D, Engineering, Manufacturing, Regulatory/QA and Clinical Studies.

Accomplishments

- Co-founded this medical device startup company, ran day-to-day operations
- Wrote business plan and gave investor presentations
- Personally responsible for raising \$2.3 million in angel investment
- Key member of the deal team which raised a total of \$12.2 million
- Created a partnership with a Korean life sciences company (Hanmi) for distribution in Asia
- Engaged, negotiated & signed an exclusive distribution agreement with J&J (Codman Division)
- Co-inventor of core enabling algorithm technologies
- Led the product development for the company's flagship patient blood flow monitor that included a minimally invasive catheter and a monitor with its associated software
- Implemented ISO 9000/13485 and oversaw the transition to ISO 13485:2003
- Recruited and collaborated with Key Opinion Leaders
- Marketed products at national surgery conferences and sold devices into key accounts
- Trained surgeons, nurses and ICU staff on the use of the device for target indications

Responsibilities

- Member of the Board of Directors (5 members total: 3 investors, 2 management)
- Hired entire technical staff, consultants and VP level personnel
- Hired key vendors, engineering firms, contract manufacturers and service providers
- Conceived, planned, and executed technology, research and product development projects
- Supervised entire technical staff (mechanical, electrical, software engineers and technicians)
- Ensured product development complied with applicable FDA and international standards
- Responsible for 510(k) FDA submissions and CE Mark applications

Thermal Technologies, Inc.

Cambridge, MA

Vice President of Research and Development and Corporate Director

1998-2000

A medical device incubator/contract research company that developed technologies for the measurement of tissue blood flow, cardiac output, tissue oxygen concentration, radiotherapy dosage and tumor temperature for use in hyperthermia therapy. Responsible for the conception, funding, and execution of original research programs.

- As Principal Investigator awarded \$3.6 million in grants from US National Institutes of Health
- Licensed core technologies from M.I.T.
- Led the development of experimental preclinical and clinical devices
- Managed an interdisciplinary team of mechanical, electrical, biomedical & software engineers
- Identified and investigated potential clinical applications for the company's technologies
- Developed international collaborations with clinicians and researchers
- Trained clinical collaborators & set up clinical research sites
- Managed contract research projects with industry, academic and government clients

Harvard-M.I.T. Division of Health Sciences and Technology at M.I.T.

Cambridge, MA

Research Staff Scientist (non-tenure track)

1996-1998

In collaboration with the Dana-Farber Cancer Institute, led a team of engineers to develop computer-based tools to aid in the treatment of tumors using hyperthermia (heat) induced by high power ultrasound. Also, wrote grants, made conference presentations, supervised graduate thesis students.

M.I.T. Biomedical Engineering Center

Cambridge, MA

Post-Doctoral Researcher

1995-1996

Researched novel technology to apply electroporation to transdermal drug delivery.

Other Activities:

MIT Enterprise Forum of Cambridge	Cambridge, MA
Vice Chair, Board of Directors	2015-present
Fractyl Laboratories, Inc.	Waltham, MA
<i>Founding member of the Business and Scientific Advisory Board</i>	2011-2014
Advised this VC-backed medical device start-up company on the design and testing of its duodenal ablation device to treat Type II Diabetes	
Maternova	Providence, RI
<i>Advisory Board Member</i>	2011-present
Advise this NGO on medical devices for maternal/neonate health in developing countries.	
Mass Challenge	Boston, MA
<i>Volunteer Mentor</i>	2010, 2013
Mentor to start-up companies in the life sciences sector, including 2013 winner Hemova Medical.	
M.I.T. Venture Mentors	Cambridge, MA
<i>Volunteer Mentor</i>	2006-2009
Advised and mentored faculty, alumni and students on the commercialization of medical devices	
US National Institutes of Health	Bethesda, MD
<i>Study Section Member, Brain Disorders and Clinical Neurosciences (BDCN-10)</i>	1999-2005
Reviewer for bioengineering grants submitted by companies, hospitals, and universities.	
Seacoast Technologies, Inc.	Portsmouth, NH
<i>Scientific Advisory Board Member and Consultant</i>	2001-2005
A VC funded start-up company that developed devices for neuro-protection after stroke using local, profound tissue cooling.	
CryoCath Technologies, Inc. (Toronto Stock Exchange: CYT)	Montreal, Quebec Canada
<i>Scientific Advisory Board Member and Consultant</i>	1996-1998
Advised the CEO and Board of Directors on the scientific direction of the device development.	
CryoCath was acquired by Medtronic in September 2008 for \$380 million.	
World Health Organization	Geneva, Switzerland
<i>Consultant and Principal Investigator</i>	1990-1993

Education:

Massachusetts Institute of Technology	Cambridge, MA
<i>Doctor of Philosophy</i>	Mechanical Engineering June 1995
<i>Master of Science</i>	Mechanical Engineering June 1991
<i>Bachelor of Science</i>	Mechanical Engineering June 1988

Executive Education:

University of Chicago, Booth School of Business,	Chicago, IL
High Performance Leadership, Negotiation, and Strategic Business Leadership	March 2010

Publications and Patents:

- More than 20 peer-reviewed scientific, engineering, and clinical publications
- 17 invited presentations.
- 9 issued US patents
- <https://scholar.google.com/citations?hl=en&user=sTxPvIAAAAAJ>

APPENDIX B

Appendix B: Materials Considered

No.	Description
1001	U.S. Patent No. 11,679,077
1003	U.S. Patent No 10,307,200 to Saadat
1005	U.S. Patent Pub. No. 2005/0240147 to Makower
1006	Fang Chao-xin and Zhen Shao-Shao, <i>Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis</i> , 25(07) J. First Mil. Medic Univ. 876 (July 20, 2005) (Translation) (“Fang”)
1008	U.S. Patent No. 6,517,535 to Edwards
1009	U.S. Patent No. 5,562,720 to Stern
1044	Chen Shi-qiang et al., <i>Preliminary study on radiofrequency thermocoagulation of the posterior inferior nerve, anterior ethmoidal nerve, and inferior turbinate under nasal endoscopy for the treatment of perennial allergic rhinitis</i> , 11(3) China Journal of Endoscopy 239 (Mar. 2005) (Translation) (“Chen”)
1056	Maureen McDaniel Sackenheim, <i>Radio Frequency Ablation</i> , JDMS 19:88-92 (March/April 2003)
1066	U.S. Patent No. 6,273,886 to Edwards (“Edwards ’886”)
1067	Joseph D. Bronzino, <i>Medical Devices and Systems</i> , The Biomedical Engineering Handbook (3rd ed. 2006)
1069	Dhanalakshmi Koyyalagunta and Danesh Mazloomdoost, <i>Radiofrequency and cryoablation for cancer pain</i> , Techniques in Regional Anesthesia and Pain Management 14:3-9 (2010)
1073	Translation Declaration for Fang
1079	Munford Appendices for Shanghai
1080	U.S. Patent No. 5,891,134 to Goble
1081	U.S. Patent No. 5,575,788 to Baker
1082	International Pub. No. 99/30655 to Hovda

APPENDIX C

Appendix C (Listing of Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[pre]	An apparatus for treating rhinitis in a nasal cavity, the apparatus comprising:	<u>Ground I</u> <u>Ground IV</u> <u>Ground V</u>
1[a]	an elongate body, comprising: a proximal portion; and a distal portion configured for positioning in the nasal cavity;	
1[b]	multiple radiofrequency electrodes coupled with the distal portion of the elongate body; and	
1[c]	a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.	
2	The apparatus of claim 1, wherein the multiple radiofrequency electrodes comprise at least two bipolar radiofrequency electrodes.	<u>Ground I</u> <u>Ground IV</u> <u>Ground V</u>
3	The apparatus of claim 2, further comprising at least one sensing electrode.	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u> <u>Ground V</u>
4	The apparatus of claim 2, wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.	<u>Ground III</u> <u>Ground IV</u> <u>Ground VI</u>
5	The apparatus of claim 1, wherein the target tissue comprises nerve tissue.	<u>Ground I</u> <u>Ground IV</u> <u>Ground V</u>

Martin Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
6	The apparatus of claim 1, wherein at least one of the multiple radiofrequency electrodes is movable relative to the distal portion of the elongate body.	<u>Ground I</u> <u>Ground IV</u> <u>Ground V</u>
7	The apparatus of claim 1, wherein the multiple radiofrequency electrodes are configured to deliver energy laterally relative to the distal portion of the elongate body.	<u>Ground I</u> <u>Ground IV</u> <u>Ground V</u>
8	The apparatus of claim 1, wherein at least one of the multiple radiofrequency electrodes is configured to extend laterally from the distal portion of the elongate body.	<u>Ground I</u> <u>Ground IV</u> <u>Ground V</u>
11	The apparatus of claim 1, further comprising a monitoring system coupled with the distal portion of the elongate body for monitoring a degree of treatment of the target tissue.	<u>Ground I</u> <u>Ground II</u> <u>Ground IV</u> <u>Ground V</u>